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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/491,624	01/26/00	DARDER	C 4948-2PCIP

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EXAMINER	
PULLIAM, A	
ART UNIT	**PAPER NUMBER**
1615	9

DATE MAILED: 08/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/491,624	DARDER, CARLOS PICORNELL	
	Examin r	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Amendment A and Priority Papers, both received June 20, 2001, as well as the Letter Transmitting Certified Copy, received July 9, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-13, 15, 16, and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Application 519 144 A1 to Tanberk *et al.*. Tanberk *et al.* disclose a method for producing pellets containing omeprazole, which is a benzimidazole. Tanberk *et al.* teach that the basic process consists of preparing an inert core, coating the inert core with an active layer, coating it with a protective coating layer, and lastly coating it with an enteric coating (p 2, l 34-37). More specifically, Tanberk *et al.* teach that the inert core contains saccharose, starch and glucose (p 2, l 41-43). The active substance (omprazole), in combination with additives such as HPMC, sodium lauryl sulfate, and lactose, is then dispersed in an aqueous solution and sprayed onto the inert pellets (p 2, l 50-58). The active coated pellets are then coated with a layer of excipients, by spraying an aqueous dispersion of HPMC onto the active coated pellets (p 3, l 1-16). Lastly, the enteric coating is applied by spraying a solution

of enteric polymer, such as HPMC phthalate, onto the already coated pellets (p 3, l 18-25). Tanberk *et al.* teach their formulation and process of making using a core and three coating layers, wherein applicant claims two coating layers. However, Tanberk *et al.* teach the same inert core ingredients, the same active ingredient, as well as the same well known excipients, and enteric polymer throughout the formulation. It is the position of the examiner that the product and process taught by Tanberk *et al.* render applicant's claims obvious, as one of ordinary skill in the art would have been motivated to use the teachings of Tanberk *et al.* to create a successful coated particle pharmaceutical formulation. The expected result would be a successful antiulcer formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-4, 6-13, 15, 16, and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Application 773 025 A1 to Ballester Rodes *et al.*. Ballester Rodes *et al.* teach a new formulation comprising benzimidazol compounds. More specifically, Ballester Rodes *et al.* teach coated an inert sugar/ starch core with a first layer consisting of the benzimidazole compound and additives, followed by another coating of a water soluble polymer such as HPMC, followed by a last coating of an enteric polymer, plasticizers, and talc (p 3, l 12-45). Ballester Rodes *et al.* disclose the generic teaching of coating an inert sugar/starch core with an active layer, as well as an enteric coating layer. Ballester Rodes *et al.* teaches their formulation and process of

making using a core and three coating layers, wherein applicant claims two coating layers. However, Ballester Rodes teaches the same inert core ingredients, the same active ingredient, as well as the same well known excipients, and enteric polymer throughout the formulation. It is the position of the examiner that the product and process taught by Ballester Rodes *et al.* render applicant's claims obvious, as one of ordinary skill in the art would have been motivated to use the teachings of Ballester Rodes *et al.* to create a successful coated particle pharmaceutical formulation. The expected result would be a successful antiulcer formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-13, and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanberk *et al.* OR Ballester Rodes *et al.* as discussed above and further in view of European Specification 244 380 B1 to Lovgren *et al.*. Tanberk *et al.* and Ballester Rodes *et al.* are described above as teaching a pharmaceutical dosage form comprising coated cores, wherein the coatings include applicant's claimed active, excipients, and enteric coating layer. Neither Tanberk *et al.* or Ballester Rodes *et al.* teach combining the active agent with an alkaline reaction compound, as specified by applicant in claims 5 and 17. Lovgren *et al.* teach a pharmaceutical formulation containing benzimidazole compounds. More specifically, Lovgren *et al.* teach a core comprising the active agent and acceptable excipients. The core is then coated with a separating or subcoating layer, followed by an enteric coating layer, each of which

comprise pharmaceutically acceptable excipients. Lovgren *et al.* is relied upon for the teaching on page 5, lines 39-42. Lovgren *et al.* teach that pharmaceutical dosage forms of acid labile substances (such as benzimidazoles) must also contain alkaline reacting constituents, in order to enhance storage stability. Therefore, it is the position of the examiner that one of ordinary skill in this art would have been motivated to combine an alkaline reacting substance with the active benzimidazole containing layer in the Ballester Rodes formulation, in order to enhance stability. The two disclosures are related, as both teach a multicoated formulation comprising benzimidazole. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed June 20, 2001 have been fully considered but they are not persuasive. Applicant's argue that the cited prior art teaches three layer systems, while applicant is claiming a two layer system. Applicant further argues that there is no motivation to alter the prior art systems in order to achieve applicant's claimed formulation. The examiner respectfully disagrees. Applicant uses comprising language in the claims, which allows for other components to be present in the composition. The expression " comprising " permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts . *See Moleculon Research Corporation v CBS , Inc 229 USPQ 805 ; In re Baxter 210 USPQ 795, 803* . Therefore, the above rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

aep
July 31, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600